



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Toxic Substances and Disease Registry**

**[30Day-22-0059]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry and the National Center for Environmental Health (ATSDR/NCEH) have submitted the information collection request titled "Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)" to the Office of Management and Budget (OMB) for review and approval. ATSDR/NCEH previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on November 16, 2021, to obtain comments from the public and affected agencies. ATSDR/NCEH received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR/NCEH will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

## Proposed Project

Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs) (OMB Control No. 0923-0059, Exp. 06/30/2022) - Revision - Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Although some PFAS are no longer produced in the United States, many remain in the environment and may impact people's health. Thus, PFAS are contaminants that have gained national prominence over the last decade.

Under Section 8006 of the Consolidated Appropriations Act, 2018, the Agency for Toxic Substances and Disease Registry and CDC's National Center for Environmental Health (ATSDR/NCEH) obtained initial approval for a three-year Paperwork Reduction Act clearance for a new information collection request (ICR). During the initial approval period, ATSDR/NCEH conducted eight exposure assessments (EAs) at current or former domestic military installations known to have PFAS in drinking water, groundwater, or any other sources of water. The information collection allowed for ATSDR/NCEH to conduct the eight EAs, with

the option for the completion of seven additional EAs at either Department of Defense (DoD) or non-DoD locations for a total of 15 EAs.

Under this Revision ICR titled "Per- or Polyfluoroalkyl Substances Exposure Assessments (PFAS EAs)" (OMB Control No. 0923-0059, Exp. 06/30/2022), ATSDR/NCEH now anticipates conducting up to three PFAS EAs each year for the next three years. This Revision will use lessons learned from the eight completed EAs to modify the methods used to conduct a maximum of nine additional EAs at either DoD or non-DoD locations. Briefly, protocol revisions include modifications to the protocol recruitment strategies (such as increasing in the number of letters of invitation per EA due to low response rates observed), allowing options to conduct door-to-door recruitment and telephone questionnaires when warranted, and modifying water intake questions to evaluate exposure that may have occurred when PFAS was present in the water.

Community Event Evaluation Survey: ATSDR/NCEH will hold a public meeting prior to the start of the EA at each EA location. The EA team will use the community event evaluation survey to receive feedback from prospective EA participants about ATSDR/NCEH's PFAS public health messaging, the enrollment process, and local feelings toward the PFAS EA project. It is assumed that approximately 250 community members will attend the public meeting to inform the community about the EA effort. Using a response rate of 65 percent, ATSDR/NCEH assume that 163

community members will fill out the community event evaluation survey at each EA location and the survey will take approximately five minutes (489 members for three EAs). The resultant time burden is 41 hours annually for three EAs.

Biological Testing Tracking: All participants, adults (864) and children (273), will be provided a biological testing tracking form when they sign in for the testing event. The form will ensure that all appropriate forms are completed and all biological samples are collected. The time associated with filling out the form as the participant moves between the various stations and the time needed to collect the biological samples is approximately 20 minutes, resulting in a burden of 379 hours annually for three EAs.

Household Eligibility Screener: ATSDR/NCEH will recruit a desired sample size of 379 respondents per EA (1,137 total per year for three EAs) using statistical household sampling methods. Eligibility criteria for individuals include specific age intervals (i.e., children older than three years given the lack of NHANES comparison data for younger children), lack of bleeding disorders that would prevent a blood draw, and time of residency (i.e., at least one year in the home prior to removal of PFAS from the drinking water).

Applying an average U.S. household size of 2.5 members, per EA, ATSDR/NCEH will enroll respondents from 152 eligible households. ATSDR/NCEH will use a response rate of 10% (65% was assumed in the original protocol) based on the response rate in

the eight completed EAs. This will require administering a five-minute household eligibility phone script to 1,520 heads-of-households per EA, or to 4,560 heads-of-households per year. The annual time burden requested for eligibility screening is 380 hours for three EAs.

Consents: All eligible respondents will be consented before being included in each EA. The consent forms will include adult consent, and parental permission and child assent forms, as appropriate. Each consented respondent will provide a serum and a urine sample. In addition, heads of households from 10% of households using tap water for their drinking water will consent to provide tap water and indoor dust samples. The consent forms will include permission to store some biospecimens and environmental samples for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. ATSDR/NCEH will also collect contact information to provide respondents with their individual sampling results. The time associated with administering the consent forms is approximately 10 minutes for 864 adults; 10 minutes for 273 parents providing permission for their children aged 3-17 years old; and 10 minutes for 115 children aged 12-17 years old who assent for themselves.

Exposure Assessment Questionnaires for Biological and Environmental Testing for Adults, Parents, or Children: ATSDR/NCEH will administer an exposure questionnaire to all consented respondents that includes questions associated with

potential exposure to PFAS both inside and outside the home (e.g., work or school). The adult questionnaire also includes several questions associated with water use and flooring type while the child questionnaire includes questions regarding playing in soil; these questions are intended to evaluate potential exposure and to support the environmental testing. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes for 864 adults; 15 minutes for 158 parents responding for their children, 3-11 years old; and 15 minutes for 115 children, 12-17 years old, who respond for themselves.

Household Recruitment Script for Environmental Sampling: The households providing environmental samples (tap water and indoor dust) will be a random 10% subset of households that report using tap water for drinking water. Assuming a 65% response rate, ATSDR/NCEH will administer a 5-minute recruitment script to 23 heads-of households who are eligible to take part in each EA. This will result in annual recruitment of 70 heads-of-households and six hours for three EAs.

Consent for Environmental Testing: ATSDR/NCEH will consent a 10% subset of households deemed eligible for the EA for testing of tap water and indoor dust samples; therefore, the desired number of households is 15 per EA, or 45 per year. The time associated with consenting to the environmental sampling is 10 minutes, resulting in a burden of eight hours annually for three EAs.

Environmental Sample Collection Form: ATSDR/NCEH will collect samples from approximately 15 households per EA or 45 households annually. The average time burden is estimated as 15 minutes per response as documented in the sample collection form.

ATSDR/NCEH estimates the total annualized time burden is 1,535 hours. This represents a decrease of 596 hours relative to the previously approved 2,131 hours. Participation is voluntary, and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
EA Community Members	Community Event Evaluation Survey	489	1	5/60
EA Participants (all ages)	Biological Testing Tracking	1,137	1	20/60
EA Adults	Household Eligibility Screener	4,560	1	5/60
	Consent	864	1	10/60
	Exposure Questionnaire (Adult) for Biological and Environmental Testing	864	1	30/60
EA Parents	Parental Permission	273	1	10/60
	Exposure Questionnaire (Child) for Biological	158	1	15/60



	Testing (Parent Proxy)			
EA Children	Assent	115	1	10/60
	Exposure Questionnaire (Child) for Biological Testing (Child completed)	115	1	15/60
EA Heads-of- Households	Household Recruitment Script for Environmental Sampling	70	1	5/60
	Environmental Sampling Consent Form	45	1	10/60
	Environmental Sample Collection Form	45	1	15/60

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